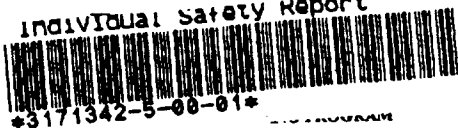


Individual Safety Report



#3171342-5-88-81*

McNEILEIL CONSUMER PRODUCTS COMPANY
FORT WASHINGTON, PA 19034

Page ____ of ____

Approved by FDA on 11/15/93

Mfr report #

UF/Dist report #

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event: 43 yrs or Date of birth: _____	3. Sex () female (X) male	4. Weight 150 lbs or kgs
In confidence			

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	() disability (X) death (mo/day/yr) 5/6/94 () life-threatening (X) hospitalization - initial or prolonged () other:

3. Date of event (mo/day/yr) 4/26/94	4. Date of this report (mo/day/yr) 11/30/94
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5. Describe event or problem

Consumer report of husband taken to hospital on 4/26/94 with CHEST PAIN. Patient developed hepatic failure & KIDNEY FAILURE, was put on life support, & expired on 5/6/94. Consumer indicated that autopsy report listed cause of death as alcohol and TYLENOL poisoning. Additional information received 11/28/94: Medical records indicate on 4/22/94, patient experienced fever, abdominal & chest pain. On 4/26/94, patient had HYPOTENSION (hypotensive episode) in ER & was admitted with HEPATIC FAILURE & treated with antibiotics & acetylcysteine discontinued 5/4/94. Patient developed kidney failure, ENCEPHALOPATHY with evidence of COAGULATION DISORDER (coagulopathy), & remained hypotensive, treated with pressors, TPN, blood products lactulose, & dialysis, & expired on 5/6/94. Final autopsy report lists principal diagnoses: massive centrilobular hepatic necrosis, diffuse alveolar damage of lungs, exudative phase & bronchopneumonia. Cause of death: massive hepatic necrosis probably due to acetaminophen toxicity.

6. Relevant tests/laboratory data, including dates

4/26/94 sys BP=70, ammonia=272, AST=5480, ALT=2251, PT=55.9, bili=8.9, WBC=31K per mm(3), serum acetaminophen level=5 mcg/ml; no source of sepsis identified, negative hepatitis serologies
5/5/94 ammonia=57, AST=143, ALT=166, PT=29, t.bili=29.1

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
alcoholic, alcoholic ulcer, history of hand surgery 2 months prior to hospitalization, no history of heart condition, treated once in 1990 for delirium tremens; allergic to penicillin

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 unknown TYLENOL product	
#2 VICODIN®	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 1000mg(4/25), 500mg(4/26)	#1 2days& unk amt 1-2 wks prior
#2 1-2 prn qday	#2 every day
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 toothache/fever	#1 () Yes () No (X) N/A
#2 Unknown	
6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2	#2
9. NDC # - for product problems only (if known)	8. Event reappeared after reintroduction
	#1 () Yes () No (X) N/A
	#2 () Yes () No (X) N/A
10. Concomitant medical products and therapy dates (exclude treatment of event) ethanol consumption of 12 pack/day for 23 years; 2-3 beers were consumed on 4/25/94	

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)	2. Phone number
McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034	215-233-7820
4. Date received by manufacturer (mo/day/yr) 11/28/94	3. Report source (check all that apply)
IND, protocol #	() foreign () study () literature (X) consumer () health professional () user facility () company representative () distributor () other:
7. Type of report (check all that apply)	
() 5-day (X) 15-day () 10-day () periodic () Initial (X) follow-up # 1	
9. Mfr. report number	8. Adverse event term(s)
0284020A	DEATH PAIN CHEST KIDNEY FAILURE LIVER FAILURE ENCEPHALOPATHY COAGULATION DIS HYPOTENSION

E. Initial reporter

1. Name, address & phone #		
Dr. _____ Hospital _____ _____ _____		
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes () No	physician	() Yes () No (X) Unk



Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.